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Fort Lauderdale Attorneys to Push FDA to Ban Essure Birth Control

by Celia Ampel

Fort Lauderdale lawyers will meet with the head of the U.S. Food and Drug Administration next month—with Erin Brockovich on hand—to push for the removal of permanent birth control device Essure from the market.

Koch Parafinczuk Wolf Susen attorneys Marcus Susen and Justin Parafinczuk represent more than 1,000 women across the country in product liability lawsuits against Bayer, Essure's manufacturer.

The lawsuits claim the contraceptive device, which includes metal coils inserted in the fallopian tubes, "migrates from the tubes, perforates organs, breaks into pieces, and/or corrodes, wreaking havoc on the female body." The FDA has received reports of deaths and miscarriages linked to use of Essure since it was first approved in 2002.

Susen and Parafinczuk will bring a group of clients to meet with FDA Commissioner Scott Gottlieb on Feb. 7, more than two years after the attorneys' lawsuits helped bring about an FDA hearing that resulted in a "black box

SEE ESSURE, PAGE A6

FROM PAGE A1

ESSURE

warning" on the product detailing significant side effects such as perforation of the uterus and persistent pain.

The FDA also ordered Bayer, whose U.S. headquarters is in Pittsburgh, Pennsylvania, to conduct a postmarket study on Essure complications over the next few years.

"We have a lot of questions, really, for Commissioner Gottlieb," Susen said of the meeting, which will also include consumer advocate Brockovich. "If the FDA required more safety studies on this product, why is it being left on the market? And why is the product still on the market in the U.S. when in all other countries, it has been withdrawn?"

According to Bayer's website, it stopped distributing Essure in other countries for "commercial reasons only." Essure is the only FDA-approved non-incisional female sterilization device, and regulators say its benefits outweigh the risks.

"It does not require general anesthesia to implant, and most women can return to normal activities within one day of receiving the implant," according to an FDA statement. "The implant does not contain drugs or hormones, and it is effective at preventing pregnancy. Banning Essure would remove the device from the market for all patients—and would limit the options available to physicians and patients."

Bayer said in a statement that it "stands behind Essure, which is an important option for women considering permanent contraception."

The South Florida lawyers started a litigation groundswell over Essure with a handful of cases they filed in Philadelphia federal court in December 2014. But their efforts illustrate the difficulties of using the court system to raise questions about a device that has already received premarket approval from the FDA.

Premarket approval preempts claims against manufacturers unless plaintiffs can establish "parallel claims" that mirror FDA regulation violations.

"It creates some additional hurdles that you have to get over before filing a lawsuit," Susen said. "That's why no attorney wanted to take this case on originally."

The Philadelphia court pared down the initial claims as the lawsuits pushed through a half-dozen motions to dismiss. The surviving claims include allegations that Bayer negligently failed to train doctors to properly insert the devices and that the company did not properly report more than 16,000 complaints about Essure to the FDA.

Other Essure lawsuits around the country include a case consolidated in California state court brought on behalf of more than 800 women. Motley Rice leads the plaintiffs executive committee there.

Bayer said the litigation has not been going well for the plaintiffs.

"To date, 47 complaints in the Essure litigation have been dismissed in their entirety or significantly narrowed largely on preemption grounds by multiple courts across the country through rulings that affect thousands of plaintiffs," according to Bayer's statement.

For its part, the FDA said it will continue to keep an eye on scientists' conclusions about Essure.

"We remain committed to the postmarketing study we ordered Bayer to conduct because it will provide answers to important questions about Essure's risks, and we will continue to provide periodic updates on that study," the FDA's statement said. "We are also continuing to monitor adverse events reported to our database, as well as other data sources, and will communicate publicly on any new findings or concerns."

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